

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Limited government-The bill increases government's role in private sector health insurance by imposing a mandated offering.

Empower families-The bill defines optional group health plan coverage of prescription and nonprescription medically necessary amino acid elemental formulas that must be covered within the mandated offering. Individuals and families may have access to amino acid elemental formula coverage through the option provided in this proposal.

B. EFFECT OF PROPOSED CHANGES:

Current Situation

Food Allergies

An estimated six to eight percent of children under the age of three suffer from food allergies.¹ Generally, when a person suffers from a food allergy, his or her immune system will release an allergic antibody upon consumption of a particular food item.² Allergic reactions to foods are not always the same. Some allergy symptoms may develop shortly after consumption or take several hours to develop. Some symptoms are localized in one particular area of the body, while others can spread throughout the body.³ The most common foods that cause allergic reactions in children are eggs, milk, peanuts, soy and soy products, wheat and wheat products, and tree nuts.⁴

Elemental Formulas to Treat Food Allergies in Infants

For infants suffering from allergies to cow's milk, physicians may prescribe soy formula or an elemental formula.⁵ Elemental formulas are produced from processed proteins with supplements (sugars and amino acids) added, and have few allergens.⁶ Elemental formulas may be administered orally or enterally, through a feeding tube surgically inserted into a child's stomach.

Currently, Florida law provides for a mandated offering of prescription and nonprescription medically necessary enteral formulas for home use for the treatment of inherited diseases of amino acid, organic acid, carbohydrate or fat metabolism as well as malabsorption originating from congenital defects present at birth or acquired during the neonatal period. Certain coverage and age limitations apply for persons with inherited diseases of amino acids and organic acids. s. 627.42395, F.S. Many insurance companies cover the costs associated with inserting a feeding tube to administer elemental formulas, and cover the cost of the formula administered through the feeding tube; however, the cost of the formula is not covered when taken orally. The weighted national estimated mean cost for feeding tube insertion based on 2003 data is \$20,242, and the weighted national estimated mean cost for enteral

¹ See "Food Allergy, An Overview," National Institute of Allergy and Infectious Diseases, Publication No. 07-5518 (July 2007); located on March 2, 2008 at <http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf>.

² *Id.*

³ K. Schneider, R. Goodrich, and M. Mahovic, "Dealing with Food Allergies," Food Science and Human Nutrition Department, Florida Cooperative Extension Service, Institute of Food and Agriculture, University of Florida, Publication No. FSHN05-13 (Aug. 2005), located on March 2, 2008 at <http://edis.ifas.ufl.edu/FS123>.

⁴ *Id.*; See also *supra* note 1.

⁵ See *supra* note 1.

⁶ *Id.*

nutrition (tube feeding) and parenteral nutrition (intravenous feeding) (principle procedure only) based on 2003 data is \$16,093.⁷

Two formulas are used for the oral consumption of elemental formula, Neocate (manufactured by Nutricia North America) and EleCare (manufactured by Abbott Laboratories). Depending on the type of Neocate formula, Neocate costs \$89 to \$139 per case, with 4 14 ounce cans per case.⁸ EleCare costs \$189 per case, with 6 14.01 ounce cans per case.⁹

Coverage of Elemental Formulas

Currently, Arizona, Connecticut, Massachusetts, New Hampshire, and New York mandate coverage for amino acid elemental formulas.¹⁰ In Florida, Medicaid reimburses for amino acid elemental formulas for Medicaid recipients under the age of 21. Medicaid's rate of reimbursement for elemental formulas is as follows:

- EleCare \$2.50 per unit
- Neocate \$2.00 per unit
- Neocate Jr. \$2.84 per unit
- Neocate One \$3.96 per unit

Each unit is 100 calories, and Medicaid reimburses up to 930 units per month.

Regulation of Health Plans

Health plans are regulated at both the state and federal level. At the federal level, the Employee Retirement Income and Security Act (ERISA) exclusively regulates, among other employer benefits, voluntary employee-sponsored (i.e., self-funded) health plans.¹¹ In contrast, private-sector health insurance plans and health maintenance organizations are generally regulated by each state.¹² Congress, however, has enacted several laws that regulate the private-sector market, including the Health Insurance Portability and Accountability Act of 1996; the Newborns' and Mothers' Health Protection Act of 1996; and the Mental Health Parity Act of 1996.

Health Insurance Mandates and Mandated Offerings

A health insurance mandate is a legal requirement that an insurance company or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Florida currently has at least¹³ 48 mandates, ranking 13th highest in the nation for the number of mandates.¹⁴ Those 48 mandates could add as much as 48 percent to the cost of health insurance in Florida.¹⁵

⁷ United States Department of Health and Human Services, Agency for Healthcare Research and Quality, HCUP.net Kids' Inpatient Database (for children aged 0-17); located on March 2, 2008 at <http://hcupnet.ahrq.gov/HCUPnet.jsp>.

⁸ See Neocate cost information on Neocate's website, located on March 2, 2008 at http://www.orderneocate.com/iwwida.pvx?products_no_tree?comp=SHS.

⁹ See EleCare cost information on manufacturer's website, located on March 2, 2008 at http://abbottnutrition.com/home/how_to_buy/index.aspx

¹⁰ See Article I, Chapter 13; Article 3, Chapter 4; and Article 5, Chapter 6 Az. Stat. Ann.; ss. 38a-492, 38a-518c, Ct. Stat. Ann.; 32A s. 17A, 175 s. 471, 176A, s. 8L, 176B, s. 4K, and 176S, s. 4D, M.G.L.A.; ss. 415:6-c, 415:18-e, 420-A:17, 420-B:8-ff N.H. Rev. Stat.; and N.Y. Insurance Law ss. 3216, 3221.

¹¹ See <http://www.dol.gov/dol/topic/health-plans/erisa.htm>.

¹² In Florida, Chapters 627 and 641, F.S., generally regulate health insurance and health maintenance organizations, respectively.

¹³ Depending on how liberally the term is defined, an alternate count indicates that there are 51 health insurance mandates in Florida. "Expanding Opportunities for Health Insurance Coverage in Florida" 11, Michael Bond, Ph.D., James Madison Institute; located on March 2, 2008 at <http://www.jamesmadison.org/pdf/materials/548.pdf>.

¹⁴ "Health Insurance Mandates in the States 2008," Council for Affordable Health Insurance; located on March 2, 2008 at http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2008.pdf.

¹⁵ Id.

Mandated offerings, on the other hand, do not mandate that certain benefits be provided. Rather, a mandated offering law can require that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require a higher premium and which the insured is free to accept or reject.

Florida enacted section 624.215, F.S., in order to take into account the impact of insurance mandates and mandated offerings on premiums when making policy decisions. That section requires that any proposal for legislation that mandates health benefit coverage or mandatorily offered health coverage must be submitted with a report to AHCA and the legislative committee having jurisdictions. The report must assess the social and financial impact of the proposed coverage, including, to the extent information is available, the following:

- (a) To what extent is the treatment or service generally used by a significant portion of the population.
- (b) To what extent is the insurance coverage generally available.
- (c) If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.
- (d) If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.
- (e) The level of public demand for the treatment or service.
- (f) The level of public demand for insurance coverage of the treatment or service.
- (g) The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.
- (h) To what extent will the coverage increase or decrease the cost of the treatment or service.
- (i) To what extent will the coverage increase the appropriate uses of the treatment or service.
- (j) To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.
- (k) To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.
- (l) The impact of this coverage on the total cost of health care.

Effect of Proposed Changes

HB 709 amends s. 627.42395, F.S., to include amino-acid-based elemental formulas, regardless of the method of intake, as a mandatory offering of coverage for policyholders of individual, group, blanket, or franchise health insurance policies as long as the formula is a medically necessary treatment for a medically diagnosed condition and ordered by a licensed physician. The bill does not define “medically necessary” or “medically diagnosed condition.” The bill provides for the types of medical conditions that may warrant the need for amino-acid-based elemental formulas, which includes severe multiple food protein allergies, gastroesophageal reflux, eosinophilic disorders, and short bowel syndrome. Such coverage must be made available to the policy holder as part of the insurance application for an appropriate additional premium, and applies to any policyholder regardless of whether a preexisting condition is present.

On March 3, 2008, proponents of the bill, Children’s Magic, Inc., offered a study pursuant to section 624.215, F.S., entitled “Report to the Legislature of the State of Florida and Florida Agency for Health Care Administration” pertaining to this bill. The report was prepared by the Collins Center for Public Policy, Inc., at the University of Florida, and by Dr. Christopher Douglas Jolley, M.D., University of Florida Department of Pediatrics.

The report states that approximately 825 children between the age of 0 and 4 in Florida suffer conditions that would warrant treatment with elemental formulas, and the cost of the formula to be

taken orally would be an estimated \$5,075 per year per child. The report states that the \$5,075 annual cost of elemental formula “is likely to pose a significant financial burden to families who must pay for the treatment out-of-pocket for their children who require it...,” and failure to provide such formula to children in need may cause children to “experience severe symptoms and complications, leading to enteral or parenteral feedings and increasing the incidence of expensive procedures.” Additionally, the report indicates that, “The mandated treatment would be less expensive than management of more severe symptoms and complications of severe multiple food protein allergy....” The study concludes that the mandate would cost \$.28 “per HMO/EPO insured”, when the costs are spread over the 5 million Floridians “insured by HMO/EPO”. The bill as currently drafted only impacts insurance policies, not HMOs.

While the study is responsive on several points, it does not identify how many of the 825 children have no health care coverage or have coverage that does not currently cover elemental formulas. It also does not assess the extent to which lack of insurance coverage results in failure to obtain the formula.

The effective date of the bill is October 1, 2008.

C. SECTION DIRECTORY:

Section 1. Amends s. 627.42395, F.S., relating to coverage for certain prescription and non-prescription enteral formulas.

Section 2. Provides an effective date of October 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See fiscal comments below.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Groups that elect to purchase the new benefit offering provided in this proposal may incur additional costs to include such coverage for amino acid elemental formulas through increased claims costs that will be passed through to policyholders in the form of increased premiums.

D. FISCAL COMMENTS:

According the Department of Management Services, if this bill passes there will be an indeterminate negative fiscal impact on State Employees Health Insurance Trust Fund.¹⁶

¹⁶ See Department of Management Services Bill Analysis.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

According to the Department of Management Services, the bill provides for possible discriminatory expanded coverage for some conditions and/or disease states over others and, because the requirements in the bill apply to health insurers only, if enacted, the bill may enable further disparity between covered benefits under the state-contracted health maintenance organization and the State Employees' PPO plan.¹⁷

The Department further states that without defining the term "medically necessary" or "medically diagnosed condition," the bill could be interpreted as making amino acid formulas "de facto medically necessary" for the conditions specified in the bill.¹⁸ Moreover, the bill does not provide for age or dollar limitations, and may require the State Employees' PPO Plan to provide coverage for experimental or investigational services.¹⁹

Finally, the Department indicated that the bill could result in the State Employees' Group Health Insurance Program removing or modifying existing covered benefits, benefit limitations, exclusions, and inpatient day limitations"²⁰

D. STATEMENT OF THE SPONSOR

One of the key points we would like to make with this bill is the formula is already covered when medically necessary. Unfortunately it is currently only covered when administered through a feeding tube. We just want to include the less invasive method of intake- through bottle or cup feeding.

Since a very small patient population will be impacted by this change it should be a cost effective approach and assist our Florida families when they face the financial crisis of not being able to afford the \$5000/yr to ensure their infants receive the proper nutrition they need. Especially considering the cost of administration through a feeding tube (\$25,000).

In reference to the staff analysis where it notes the study did not identify how many of the 825 children impacted by this condition had no coverage and were insured but there was no coverage for the formula, I offer the following: 825 infants impacted, 239 covered by WIC, 305 insured but formula not covered and the remaining 321 infants are either uninsured or have coverage under self-insured plans that will not be impacted by this legislation.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

We are also offering a strike all amendment to address the correct statute of reference and to define medical necessity as requested in the staff analysis. The bottom line is this legislation will aid the middle class families who struggle to cover the costs of their infant's formula and are faced with a difficult decision of finding an additional \$400/month to feed their child or have them go through an invasive procedure in order to continue to thrive.

Thank you for your consideration of this good bill.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES